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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,887	02/20/2002	Jerome F. McAleer	SELF.P-016-3	1254

27777 7590 06/30/2005

PHILIP S. JOHNSON  
JOHNSON & JOHNSON  
ONE JOHNSON & JOHNSON PLAZA  
NEW BRUNSWICK, NJ 08933-7003

EXAMINER
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NOGUEROLA, ALEXANDER STEPHAN

ART UNIT	PAPER NUMBER
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1753

DATE MAILED: 06/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/869,887

Applicant(s)

MCALEER ET AL.

Examiner

ALEX NOGUEROLA

Art Unit

1753

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10 and 12-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 12-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>05/02/2005</u> . | 6) <input checked="" type="checkbox"/> Other: <u>2<sup>nd</sup> IDS of 05/02/2005</u> . |

## **DETAILED ACTION**

### ***Claim Objections***

1. Claims 1 and 12 are objected to because of the following informalities:
  - a) Claim 1, line 19: "en" should be – an --;
  - b) Claim 1, line 22: -- a – should be inserted between "having" and "first";
  - c) Claim 1, line 2: "and electrochemical" should be -- an electrochemical --
  - d) Claim 12, line 19: -- a – should be inserted between "having" and "first".

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

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a) Claim 1 recites the limitation "the first conductive species" in lines 15-16.

There is insufficient antecedent basis for this limitation in the claim.

4. Note that dependent claims will have the deficiencies of base and intervening claims.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

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the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1-10 and 14 are rejected under 35 U.S.C. 103(a) as being obvious over McAleer et al. (US 5,708,247) ("McAleer I") in view of Pollman (US 5,288,636) ("Pollman").

The applied reference has common inventors with the instant application. Oliver Davies, however, is not listed as an inventor on the McAleer I patent. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in

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accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(I)(1) and § 706.02(I)(2).

Addressing claims 1 and 14, McAleer I discloses a disposable test strip for use in a test meter of the type which receives a disposable test strip and a sample of blood and performs an electrochemical analysis of the amount of a blood analyte in a sample (abstract), comprising

- (a) a substrate (10);
- (b) a first conductive element (14) disposed on the substrate;
- (c) a second conductive element (15) disposed on the substrate in sufficient proximity to the first conductive element to allow the completion of an electrical circuit between the first and second conductive elements when a sample of blood is placed on the test strip (Figure 1A);
- (d) a non-conductive integrated reagent/blood separation layer (17) disposed over the first conductive element, the integrated reagent /blood separation layer comprising reagents for the electrochemical detection of the analyte dispersed in a non-conductive matrix effective to exclude blood cells from the surface of the first conductive element while permitting access to the first conductive element by soluble electroactive species (col. 4:35-57);
- (e) contacts for making an electrical connection between the first and second conductive elements and the test meter (11, 12); and

(f) an insulation layer (18) disposed over at least the first conductive elements, the insulation layer having a first aperture therein aligned with the first conductive element, wherein the non-conductive integrated reagent/blood separation layer contacts the first conductive element through the aperture in the insulation layer and wherein the non-conductive integrated reagent/blood separation layer is formed covering the entire first aperture, thereby leaving no portion of the first conductive element directly exposed to a sample applied to the test strip (see Figures 1A and 1B and col. 5:50 col. 6:16).

McAleer I does not mention having the pH of the integrated reagent/blood separation layer buffered to a level of around pH 5. Pollmann teaches a disposable test strip comprising at least two conductive elements with a reagent layer adjacent the conductive elements, the reagent layer including a redox mediator, an enzyme, and a buffer. See the abstract and Figures 1-3. Pollmann further teaches using a citrate buffer (col. 7:59-61), which Applicants implicitly acknowledge buffers to around pH 5 (see claim 11). It would have been obvious to one with ordinary skill in the art at the time the invention was made to use buffer as taught by Pollmann in the invention of McAleer I because as taught by Pollmann the buffer will provide a satisfactory pH for enzymatic activity. See col. 4:13-17 and col. 7:55-58. More particularly, it would have been obvious to use citrate buffer because Pollmann teaches that citrate helps stabilize glucose oxidase (see claim 9 of the instant application). Alternatively, the choice of buffer (pH) from known buffers in the art is just a matter of optimizing the enzymatic

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reaction as it was known at the time of the invention that most enzymes have limited active pH ranges.

Addressing claim 2, for the additional limitation of this claim see col. 4:4-9

Addressing claim 3, for the additional limitation of this claim see col. 4:10-34

Addressing claims 4 and 8, for the additional limitation of this claim see col. 3:55-

60

Addressing claims 5 and 9, for the additional limitation of this claim see col. 4:5-9 and col. 5:44-50

Addressing claims 6 and 10, for the additional limitation of this claim see col. 4:5-9 and col. 5:44-50

Addressing claim 7, for the additional limitation of this claim see claim 19 of McAleer I



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9. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being obvious over McAleer et al. (US 5,708,247) ("McAleer I").

The applied reference has common inventors with the instant application. Oliver Davies, however, is not listed as an inventor on the McAleer I patent. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(I)(1) and § 706.02(I)(2).

Addressing claim 12, McAleer I discloses a disposable test strip for use in a test meter of the type which receives a disposable test strip and a sample of blood and performs an electrochemical analysis of the amount of a blood analyte in a sample (abstract), comprising

(a) a substrate (10);

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- (b) a first conductive element (14) disposed on the substrate;
- (c) a second conductive element (15) disposed on the substrate in sufficient proximity to the first conductive element to allow the completion of an electrical circuit between the first and second conductive elements when a sample of blood is placed on the test strip (Figure 1A);
- (d) a non-conductive integrated reagent/blood separation layer (17) disposed over the first conductive element, the integrated reagent /blood separation layer comprising reagents for the electrochemical detection of the analyte dispersed in silica fillers effective to exclude blood cells from the surface of the first conductive element while permitting access to the first conductive element by soluble electroactive species (col. 4:4-57);
- (e) an insulation layer (18) disposed over at least the first conductive elements, the insulation layer having a first aperture therein aligned with the first conductive element, wherein the non-conductive integrated reagent/blood separation layer contacts the first conductive element through the aperture in the insulation layer and wherein the non-conductive integrated reagent/blood separation layer is formed covering the entire first aperture, thereby leaving no portion of the first conductive element directly exposed to a sample applied to the test strip (see Figures 1A and 1B and col. 5:50 col. 6:16).

Addressing claim 13, for the additional limitation of this claim see col. 4:58-62 and note the disclosure of at least hydroxyethylcellulose.

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10. Claims 1-10 and 14 are rejected under 35 U.S.C. 103(a) as being obvious over McAleer et al. (US 5,951,836) ("McAleer II") in view of Pollman (US 5,288,636) ("Pollman").

The applied reference has common inventors with the instant application. Oliver Davies, however, is not listed as an inventor on the McAleer II patent. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(I)(1) and § 706.02(I)(2).

Addressing claims 1 and 14, McAleer II discloses a disposable test strip for use in a test meter of the type which receives a disposable test strip and a sample of blood and performs an electrochemical analysis of the amount of a blood analyte in a sample (abstract), comprising

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- (a) a substrate (10);
- (b) a first conductive element (14) disposed on the substrate;
- (c) a second conductive element (15) disposed on the substrate in sufficient proximity to the first conductive element to allow the completion of an electrical circuit between the first and second conductive elements when a sample of blood is placed on the test strip (Figure 1A);
- (d) a non-conductive integrated reagent/blood separation layer (17) disposed over the first conductive element, the integrated reagent /blood separation layer comprising reagents for the electrochemical detection of the analyte dispersed in a non-conductive matrix effective to exclude blood cells from the surface of the first conductive element while permitting access to the first conductive element by soluble electroactive species (col. 4:39-61);
- (e) contacts for making an electrical connection between the first and second conductive elements and the test meter (11, 12); and
- (f) an insulation layer (18) disposed over at least the first conductive elements, the insulation layer having a first aperture therein aligned with the first conductive element, wherein the non-conductive integrated reagent/blood separation layer contacts the first conductive element through the aperture in the insulation layer and wherein the non-conductive integrated reagent/blood separation layer is formed covering the entire first aperture, thereby leaving no portion of the first conductive element directly exposed to a sample applied to the test strip (see Figures 1A and 1B and col. 5:55 col. 6:21).

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McAleer I does not mention having the pH of the integrated reagent/blood separation layer buffered to a level of around pH 5. Pollmann teaches a disposable test strip comprising at least two conductive elements with a reagent layer adjacent the conductive elements, the reagent layer including a redox mediator, an enzyme, and a buffer. See the abstract and Figures 1-3. Pollmann further teaches using a citrate buffer (col. 7:59-61), which Applicants implicitly acknowledge buffers to around pH 5 (see claim 11). It would have been obvious to one with ordinary skill in the art at the time the invention was made to use buffer as taught by Pollmann in the invention of McAleer I because as taught by Pollmann the buffer will provide a satisfactory pH for enzymatic activity. See col. 4:13-17 and col. 7:55-58. More particularly, it would have been obvious to use citrate buffer because Pollmann teaches that citrate helps stabilize glucose oxidase (see claim 9 of the instant application). Alternatively, the choice of buffer (pH) from known buffers in the art is just a matter of optimizing the enzymatic reaction as it was known at the time of the invention that most enzymes have limited active pH ranges.

Addressing claim 2, for the additional limitation of this claim see col. 4:7-12

Addressing claim 3, for the additional limitation of this claim see col. 4:7-38

Addressing claims 4 and 8, for the additional limitation of this claim see col. 3:58-

Addressing claims 5 and 9, for the additional limitation of this claim see col. 4:7-12 and col. 5:48-53

Addressing claims 6 and 10, for the additional limitation of this claim see col. 4:7-12 and col. 5:48-53

Addressing claim 7, for the additional limitation of this claim see col. 4:62 – col. 5:6, which has the same specified ranges or ranges that significantly overlap the claimed ranges.

11. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being obvious over McAleer et al. (US 5,951,836) ("McAleer II").

The applied reference has common inventors with the instant application. Oliver Davies, however, is not listed as an inventor on the McAleer II patent. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the

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application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(I)(1) and § 706.02(I)(2).

Addressing claim 12, McAleer II discloses a disposable test strip for use in a test meter of the type which receives a disposable test strip and a sample of blood and performs an electrochemical analysis of the amount of a blood analyte in a sample (abstract), comprising

- (a) a substrate (10);
- (b) a first conductive element (14) disposed on the substrate;
- (c) a second conductive element (15) disposed on the substrate in sufficient proximity to the first conductive element to allow the completion of an electrical circuit between the first and second conductive elements when a sample of blood is placed on the test strip (Figure 1A);
- (d) a non-conductive integrated reagent/blood separation layer (17) disposed over the first conductive element, the integrated reagent /blood separation layer comprising reagents for the electrochemical detection of the analyte dispersed in a non-conductive matrix effective to exclude blood cells from the surface of the

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first conductive element while permitting access to the first conductive element by soluble electroactive species (col. 4:7-61);

(f) an insulation layer (18) disposed over at least the first conductive elements, the insulation layer having a first aperture therein aligned with the first conductive element, wherein the non-conductive integrated reagent/blood separation layer contacts the first conductive element through the aperture in the insulation layer and wherein the non-conductive integrated reagent/blood separation layer is formed covering the entire first aperture, thereby leaving no portion of the first conductive element directly exposed to a sample applied to the test strip (see Figures 1A and 1B and col. 5:55 col. 6:21).

McAleer I does not mention having the pH of the integrated reagent/blood separation layer buffered to a level of around pH 5. Pollmann teaches a disposable test strip comprising at least two conductive elements with a reagent layer adjacent the conductive elements, the reagent layer including a redox mediator, an enzyme, and a buffer. See the abstract and Figures 1-3. Pollmann further teaches using a citrate buffer (col. 7:59-61), which Applicants implicitly acknowledge buffers to around pH 5 (see claim 11). It would have been obvious to one with ordinary skill in the art at the time the invention was made to use buffer as taught by Pollmann in the invention of McAleer I because as taught by Pollmann the buffer will provide a satisfactory pH for enzymatic activity. See col. 4:13-17 and col. 7:55-58. More particularly, it would have been obvious to use citrate buffer because Pollmann teaches that citrate helps stabilize glucose oxidase (see claim 9 of the instant application). Alternatively, the choice of



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buffer (pH) from known buffers in the art is just a matter of optimizing the enzymatic reaction as it was known at the time of the invention that most enzymes have limited active pH ranges.

Addressing claim 13, for the additional limitation of this claim see col. 4:62-66 and note the disclosure of at least hydroxyethylcellulose.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Alex Noguerola  
Primary Examiner  
AU 1753  
June 26, 2005